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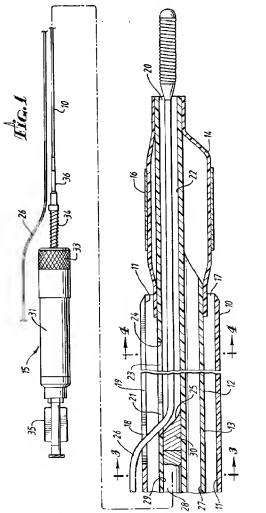
(54) Stent delivery system.

(57) The invention is directed to a stent delivery method and system which generally includes an elongated delivery sheath (10) and a catheter (12) disposed within an inner lumen (11) of the sheath (10) having an expandable member (14) on its distal extremity. An expandable stent (16) is mounted on the expandable member (14) of the catheter (12). A manipulating device (15) is provided on the proximal end of the delivery system to effect relative axial movement between the sheath (10) and the catheter (12) so as to expose the stent (16) mounted on the expandable member (14) on the catheter (12) within a body lumen such as a coronary artery and allow the expansion of the stent (16) by the expansion of the expandable member (14). The delivery sheath (10) has a first port (17) in its distal end and a second port (18) in the sheath wall proximally disposed from the distal end of the sheath (10). The catheter (12) likewise has a first port (20) in its distal end and a second port (21) proximally disposed from the distal end of the catheter (12). An inner lumen (22) extends within the distal portion of the catheter (12) between the first and second ports (20, 21) and slidably receives a guiding member such as a guidewire (26). This system allows the stent (16) to be delivered over a guidewire (26) previously advanced to the desired location within a body lumen.



EP 0 505 686 A1

BACKGROUND OF THE INVENTION

This invention relates to devices and a method for the treatment of heart disease and particularly to endo-arterial prosthesis, which are commonly called stents.

Several interventional treatment modalities are presently used for heart disease including balloon and laser angioplasty, atherectomy and by-pass surgery.

In typical balloon angioplasty procedures a guiding catheter having a preformed distal tip is percutaneously introduced through the femoral artery into the cardiovascular system of a patient in a conventional Seldinger technique and advanced within the cardiovascular system until the distal tip of the guiding catheter is seated in the ostium of a desired coronary artery. A guidewire is positioned within an inner lumen of a dilatation catheter and then both are advanced through the guiding catheter to the distal end thereof. The guidewire is first advanced out of the distal end of the guiding catheter into the patient's coronary vasculature until the distal end of the guidewire crosses a lesion to be dilated, then the dilatation catheter having an inflatable balloon on the distal portion thereof is advanced into the patient's coronary anatomy over the previously introduced guidewire until the balloon of the dilatation catheter is properly positioned across the lesion. Once in position across the lesion, the balloon which is made of relatively inelastic materials is inflated to a predetermined size with radiopaque liquid at relatively high pressures (e.g. greater than 4 atmospheres) to compress the arteriosclerotic plaque of the lesion against the inside of the artery wall and to otherwise expand the inner lumen of the artery. The balloon is then deflated so that blood flow can be resumed through the dilated artery and the dilatation catheter can be removed therefrom. Further details of dilatation catheters, guidewires, and devices associated therewith for angioplasty procedures can be found in U.S. Patent 4,323,071 (Simpson-Robert); U.S. Patent 4,439,185 (Lundquist); U.S. Patent 4,516,972 (Samson); U.S. Patent 4,538,622 (Samson *et al.*); U.S. Patent 4,554,929 (Samson *et al.*); U.S. Patent 4,616,652 (Simpson); U.S. Patent 4,638,805 (Powell); and U.S. Patent 4,748,982 (Horzewski *et al.*) which are hereby incorporated herein in their entirety by reference thereto.

A major problem which can occur during balloon angioplasty procedures is the formation of intimal flaps which can collapse and occlude the artery when the balloon is deflated at the end of the angioplasty procedure. Another major problem characteristic of balloon angioplasty procedures is the large number of patients which are subject to restenosis in the treated artery. In the case of restenosis, the treated artery may again be subjected to balloon angioplasty or to other treatments such as by-pass surgery, if additional balloon angioplasty procedures are not warranted. However, in the event of a partial or total occlusion of a coronary artery by the collapse of a dissected arterial lining after the balloon is deflated, the patient is put in an extremely dangerous situation requiring immediate medical attention, particularly in the coronary arteries.

A major focus of recent development work in the treatment of heart disease has been directed to endoprosthetic devices called stents. Stents are generally cylindrically shaped intravascular devices which are placed within a damaged artery to hold it open. The device can be used to prevent restenosis and to maintain the patency of blood vessel immediately after intravascular treatments. In some circumstances, they can also be used as the primary treatment device where they are expanded to dilate a stenosis and then left in place.

However, the rapid and effective delivery of a stent to the desired location within the patient's vasculature has been found to be difficult, particularly in those situations in which an intimal flap has occluded an artery. Attempts to advance a stent into regions of coronary arteries occluded by dissected arterial linings have not been very successful.

Two basic methods and systems have been developed for delivering stents to desired locations within body lumens. One method and system involves compressing or otherwise reducing the diameter of an expandable stent, disposing the compressed stent within a lumen provided in the distal end of a tubular catheter, advancing the catheter through the patient's vasculature until the distal end of the catheter is immediately adjacent to the desired vascular location and then pushing the stent out the distal end of the catheter into the desired location. Once out of the catheter, the compressed stent expands or is expanded to thereby hold open the artery or other body lumen into which it is placed.

Another method and system involves disposing a compressed or otherwise small diameter stent about an expandable member such as a balloon on the distal end of a catheter, advancing the catheter through the patient's vascular system until the stent is in the desired location within a blood vessel and then expanding the expandable member on the catheter to expand the stent within the blood vessel. The expanded expandable member is then contracted and the catheter withdrawn, leaving the expanded stent within the blood vessel holding open the passageway thereof.

The following references illustrate various types of stents and stent delivery systems. The list is meant to be exemplary not exhaustive on the subject.

U.S. 3,868,956	U.S. 4,733,665	U.S. 4,856,516
U.S. 4,503,569	U.S. 4,760,849	U.S. 4,878,906
U.S. 4.512,338	U.S. 4,762,128	U.S. 4,886,062
U.S. 4,553,545	U.S. 4,768,507	U.S. 4,907,336
U.S. 4,560,374	U.S. 4,795,458	U.S. 4,913,141
U.S. 4,655,771	U.S. 4,800,882	U.S. 4,923,464
U.S. 4,665,918	U.S. 4,830,003	U.S. 4,950,227

What has been needed and heretofore unavailable is a stent delivery system which can be quickly and easily used in a wide variety of situations and particularly in emergency situations where a dissected arterial lining has collapsed and has occluded the flow of blood to a vital organ. The present invention satisfies this need.

SUMMARY OF THE INVENTION

This invention is directed to an improved stent delivery system which can quickly and easily position a stent into an occluded region of a blood vessel.

The stent delivery system of the invention includes an elongated sheath having an inner lumen extending therein, a first port in its distal end which is adapted to receive a guidewire and a second port spaced proximally from the distal end of the delivery sheath which is also adapted to receive a guidewire, both of the ports being in fluid communication with the inner lumen of the sheath. The delivery system also includes an intravascular catheter slidably disposed within the inner lumen of the delivery sheath which has an expandable member on the distal extremity thereof, such as an inflatable balloon, which is adapted to receive an expandable stent on the exterior thereof. The catheter has a first port in its distal end adapted to receive a guidewire and a second port spaced proximally from the distal end of the catheter adapted to receive a guidewire, with both of these ports being in communication with an inner lumen extending within the interior of the catheter. The second guidewire receiving port should be spaced proximally from the expandable member on the distal extremity of the catheter. Means may be provided to adjust the relative axial positions of the catheter and sheath to expose the expandable stent on the expandable member of the catheter so that the stent can be expanded against the blood vessel wall by expanding the expandable member.

Preferably, both the delivery sheath and the intravascular catheter have slits in the walls thereof which extend distally from their proximal ports to facilitate the removal of these devices from the guidewire upon the withdrawal of the delivery system from the patient's vascular system after the delivery of a stent.

In a typical situation, the guidewire used to deliver a dilatation catheter through the patient's vascular system to a stenotic region therein is left disposed within the patient after the dilatation catheter has been removed therefrom. To maintain access to the stenotic region, the distal end of the guidewire should be left crossing the stenotic region where the stent is to be placed. The proximal end of the guidewire, which extends out of the patient, is inserted through the port in the distal end of the intravascular catheter which has a stent mounted on the expandable member. The intravascular catheter is disposed within the inner lumen of the delivery sheath with the distal end of the catheter extending out the port in the distal end of the delivery sheath to facilitate the insertion of the proximal end of the guidewire. The relative axial position between the delivery sheath and intravascular catheter are adjusted so that the expandable member on the distal extremity of the intravascular catheter with the expandable stent mounted thereon is pulled back into the inner lumen of the delivery sheath. The delivery sheath and the catheter therein are then advanced through the patient's vascular system, preferably through a guiding catheter which extends from outside the patient to the ostium of the desired coronary artery, until the stent mounted on the expandable member of the intravascular catheter is positioned within the stenotic region of the patient's blood vessel.

The relative axial positions of the delivery sheath and the intravascular catheter having the stent thereon is adjusted to urge the distal end of the vascular catheter out the distal end of the sheath to expose the expand-

able stent. Either the catheter can be advanced distally with respect to the sheath or the sheath can be withdrawn proximally with respect to the catheter or both movements can be employed. Once the stent is completely out of the delivery sheath, the expandable member on the intravascular catheter can be expanded to expand the stent against stenotic mass within the blood vessel. After expanding the stent, the expandable member on the vascular catheter is contracted so that the catheter can be removed from the patient's blood vessel leaving the expanded stent in its desired position therein.

The delivery sheath and the intravascular catheter may be withdrawn together or the sheath may be withdrawn first followed by withdrawal of the catheter. They are removed over the guidewire until the proximal guidewire port on the sheath and/or the catheter exits the proximal end of the guiding catheter, the sheath and the catheter can be poled away from the guidewire with the guidewire sliding through the slits which extend distally from the proximal ports thereof. The sheath and the intravascular catheter are pulled proximally out of the proximal end of the guiding catheter a sufficient distance to expose the guidewire. The exposed section of the guidewire is secured, *e.g.* manually held, in place so that the sheath and the intravascular catheter can be pulled off the proximal end of the guidewire.

The delivery system of the invention can effectively deliver a stent to a desired location within a patient's blood vessel, it can allow the stent to be secured within the desired location, and the can be easily and quickly removed. These and other advantages of the invention will become more apparent from the following detailed description of the invention, when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a partial longitudinal cross-sectional view of a stent delivery system which embodies features of the invention.

Fig. 2 is a top view of the delivery sheath shown in Fig. 1.

Fig. 3 is a transverse cross-sectional view taken along the lines 3-3 shown in Fig. 1.

Fig. 4 is a transverse cross-sectional view taken along the lines 4-4 shown in Fig. 1.

Fig. 5 illustrates a stent mounted on the outer surface of a balloon of the dilatation catheter shown in Fig. 1.

Fig. 6 illustrates the advancement of the stent delivery system shown in Fig. 5 into an artery which has been damaged by an intravascular procedure such as an angioplasty.

Fig. 7 illustrates the inflation of the balloon on the dilatation catheter shown in Fig. 1 which expands the stent mounted on the exterior thereof.

Fig. 8 illustrates the expanded stent disposed within a damaged arterial section maintaining the patency thereof.

Fig. 9 is a partial cross-sectional view of the manipulator shown in Fig. 1.

Fig. 10 is a perspective view of an alternative manipulator mounted on the proximal end of the delivery system shown in Fig. 1.

Fig. 11 is a plan view of the manipulator shown in Fig. 10.

Fig. 12 is an elevational view, partially in section, of the manipulator shown in Fig. 10.

DETAILED DESCRIPTION OF THE INVENTION

Figs. 1-4 illustrate a stent delivery system which embodies features of the invention. Generally, the delivery system includes a delivery sheath 10 which has an inner lumen 11 and a dilatation catheter 12 disposed within the inner lumen 11 which has an elongated catheter body 13 and a balloon 14 on the distal portion of the catheter body. A manipulating device 15 is provided on the distal end of the delivery system which is employed to effect relative axial or longitudinal movement between the delivery sheath 10 and the dilatation catheter 12. An expandable stent 16, which is to be delivered within a patient's body lumen, is mounted on the exterior of the balloon 14.

The delivery sheath 10 has a distal port 17 in its distal end which is in fluid communication with the inner lumen 11 and a proximal port 18 disposed proximally to the distal port. A slit 19 extends from the proximal port 18 to a location just proximal to the distal port 17.

The dilatation catheter 12 has a distal port 20 and a proximal port 21 which are in fluid communication with a first inner lumen 22 extending within the distal portion of the catheter 12 and being adapted to slidably receive a guidewire therein. A slit 23 extends from the proximal port 21 to a location 24 proximal to the proximal end of balloon 14. The proximal end of the guidewire receiving lumen 22 is provided with a ramp 25 to guide the proximal end of guidewire 26 out the proximal port 21 in the catheter 12 when the catheter is mounted onto the guidewire as will be discussed hereinafter. A second, much longer inner lumen 27 is provided within the catheter

body 13 to direct inflation fluid from the proximal end of the catheter body to the interior of the balloon 14.

Proximal to the proximal port 21 in the catheter body 13 is a stiffening member 28 which is disposed in third inner lumen 29 provided within the catheter body 13. As shown in the drawings, the third inner lumen 29 and the first inner lumen 22 may be the same lumen with a plug 30 separating the two lumens. The ramp 25 is on the distal side of the plug 30.

As illustrated in Figs. 1 and 8, the manipulator 15 on the proximal end of the delivery system has a housing 31 with an interior chamber 32, a cap 33 rotatably mounted onto the distal end of the housing 31, an elongated drive member 34 which has male threads on the exterior thereof and which is at least partially disposed within the interior chamber 32 and a Luer lock 35 which is fixed within the proximal end of the housing 31. The proximal end 36 of the sheath 10 is secured to the distal end 37 of the elongated drive member 34 which extends out of the distal end of the housing 31. As shown in more detail in Fig. 8, the proximal end 38 of the catheter body 13 passes through passageway 39 in the elongated drive member 34 and is fixed within the Luer lock 35 by suitable means such as adhesive. The cap 33 which is rotatably mounted onto the distal end of the housing 31 is provided with an inner threaded collar 40 adapted to threadably engage the threaded exterior of the elongated driving member 34. Rotation of the cap 31 axially moves the driving member 34 to thereby effect relative axial movement between the sheath 10 and the dilatation catheter 12.

In a typical situation, the stent delivery system of the invention is used after an intravascular procedure has damaged a patient's arterial lining to such an extent that the lining needs support to prevent it from collapsing into the arterial passageway and thereby preventing sufficient blood flow through the blood vessel. In these situations there will usually be a guidewire 26 (or other guiding member) in place extending across the damaged section of the artery such as shown in Fig. 6. The proximal end of the guidewire 26, which extends out of the patient during the entire procedure, is inserted through the distal port 20 in the distal end of the catheter 12 and advanced proximally through the first inner lumen 22 until the proximal end of the guidewire impacts the ramp 25 and is thereby directed through the proximal port 21.

The dilatation catheter 12 is preferably positioned within the inner lumen 11 of the delivery sheath 10 so that at least a significant portion of the proximal port 18 in the sheath is in alignment with the proximal port 21 of the dilatation catheter. In this manner, proximal advancement of the guidewire 26 through the inner lumen 22 will also direct the proximal end of the guidewire out the proximal port 18 in the delivery sheath 10. The proximal end of the guidewire 26 may then be manually held to maintain the position of the guidewire within the patient's vasculature, while the stent delivery system is advanced over the guidewire system. The advancement of the stent delivery system continues until the distal ends of the catheter and sheath extend adjacent to or across the damaged arterial site. At this point in the procedure, the manipulator 15 on the proximal end of the delivery system is actuated by rotating the cap 33 on the proximal end of the housing 31 to move the sheath 10 proximally with respect to the catheter 12 and thereby expose the stent 16 mounted on the balloon 14. When the balloon and the stent mounted thereon are properly placed within the damaged artery, inflation fluid is directed under substantial pressure through the Luer lock 35 and the inflation lumen 27 in the catheter body 13 to the interior of the balloon 14, expanding the balloon and simultaneously expanding the stent 16 against the blood vessel wall as shown in Fig. 7. The delivery system, both the sheath 10 and the catheter 12, may then be removed from the patient along with the guidewire 26, leaving the expanded stent 16 within the damaged arterial section as shown in Fig. 8 to maintain the patency thereof.

The housing 31 of the manipulator 15 can be held in the palm of the physician's hand, with the thumb and index finger thereof used to rotate cap 33 and thereby cause the necessary relative motion between the sheath 10 and dilatation catheter 12 to expose the stent 16 mounted on the balloon 14. The physician can operate an inflation device, such as described in U.S.Patent 4,439,185, with his or her free hand to inject inflation fluid through Luer lock 35 into the interior of the balloon 14 to inflate the balloon and thereby expand the stent 16 while holding the delivery system in place with the other hand. Upon deflating the balloon 14, the manipulator 15 can again be actuated by the physician rotating cap 33 with the fingers of the hand holding the manipulator 15 to pull the dilatation catheter 12 back into the distal end of the sheath 10 (or pushing the distal end of the sheath over the distal end of the dilatation catheter 12, depending upon the perspective) and then the entire assembly, including the guidewire 26 can be removed from the patient.

The alternative manipulator 50 illustrated in Figs.10-12 generally includes a housing 51 with an interior chamber 52 and a slidable element 53 with a depending portion 54 which extends through a slot 55 in the wall of the housing and is secured to the proximal end of the sheath 10 which extends through an opening provided in the distal end of the housing. The catheter 12 extends out the proximal end of the sheath 10, out an opening in the proximal end of the housing 51 and into a Luer lock 56 secured to the proximal end of the housing. The proximal end of the catheter 12 is secured within the Luer lock 56 to be in fluid communication with the inner inflation lumen 27 of the catheter so that inflation fluid can be injected through the Luer lock to the interior of the balloon 14 on the catheter to expand the balloon and the stent 16 mounted thereon. As is evident from Fig.

10, movement of element 53 on the exterior of the housing 51 will effect the relative axial movement between the delivery sheath 10 and the catheter 12 required to expose the stent 16 mounted on the balloon 14. The slot 55 has narrowed portions near both ends thereof which have widths just lightly smaller than the depending element 54 so that the position of the slidable element 53 can be locked.The underside of the housing 51 may be provided with an undulated surface 57 which is adapted to receive the fingers of an operator to facilitate the gripping thereof.

The dimensions of the dilatation catheter will generally follow the dimensions of dilatation catheters used in angioplasty procedures in the same arterial location. Typically, the length of a catheter for use in the coronary arteries is about 150 cm, the outer diameter of the catheter shaft is about 0.035 inch (0.89 mm), the length of the balloon is typically about 2 cm and the inflated diameter about 1 to about 8 mm.

The materials of construction may be selected from those used in conventional balloon angioplasty catheters, such as those described in the patents incorporated by reference. The delivery sheath will generally be slightly shorter than the dilatation catheter, *e.g.* by about the length of the manipulating device 15 or 50, with an inner diameter large enough to accommodate the dilatation catheter and allow the catheter free longitudinal movement therein. The sheath and the catheter shaft can be made of conventional polyethylene tubing.

While the present invention has been described herein in terms of delivering an expandable stent to a desired location within a patient's blood vessel, the delivery system can be employed to deliver stents to locations within other body lumens such as urethra or Fallopian tubes so that the stents can be expanded to maintain the patency of these body lumens. Various changes and improvements may also be made to the invention without departing from the scope thereof.

Claims

1. A system for the delivery of an expandable stent within a body lumen over a guiding member comprising:
   a) an elongated sheath having proximal and distal ends, an inner lumen extending therein, a first port in the distal end and a second port spaced proximally from the distal end, both of the ports being in fluid communication with the inner lumen;
   b) an elongated catheter disposed within the inner lumen of the sheath having proximal and distal ends, an expandable member proximally adjacent to the distal end of the catheter which is adapted to receive on the exterior thereof an expandable stent, and an inner lumen which is adapted to slidably receive a guiding member therein and which extends between a first port in the distal end of the catheter and a second port spaced proximally from the distal end of the catheter, both of the ports being in fluid communication with the inner lumen of the catheter; and
   c) means to adjust the relative axial positions of the catheter and the sheath to expose the expandable member on the catheter so that upon the expansion of the expandable member an expandable stent disposed about the expandable member will thereby be expanded.

2. The stent delivery system of claim 1 wherein the sheath has a wall with a slit therein extending between the first and second ports thereof.

3. The stent delivery system of claims 1 or 2 wherein the catheter has a wall with a slit therein extending from the second port to a location proximal to the expandable member.

4. The stent delivery system of any one of the preceding claims wherein the means to adjust the relative axial positions of the dilatation catheter and the sheath includes a manipulator comprising:
   an elongated housing having proximal and distal ends and an interior chamber;
   a cap which has a threaded passageway therethrough and which is rotatably mounted on an end of the elongated housing; and
   a longitudinally movable drive member which has a threaded exterior, which is disposed at least partially within the interior chamber of the elongated housing and which has a distal end extending through the central passageway of the cap, rotation of the cap causing movement of the axial movement of drive member.

5. The stent delivery system of claim 4 wherein the longitudinally movable drive member has a central passageway which receives the proximal end of the catheter.

6. The stent delivery system of claim 5 wherein the proximal end of the catheter is fixed to the manipulator

housing.

7. The stent delivery system of claims 5 or 6 wherein the sheath is fixed to the distal end of the longitudinally movable drive member which extends out the distal end of the manipulator.

8. A kit for the delivery of a stent within a body lumen comprising:
a) an elongated sheath having proximal and distal ends, an inner lumen extending therein, a first port in the distal end and a second port spaced proximally from the distal end, both of the ports being in fluid communication with the inner lumen;
b) an elongated catheter adapted to be disposed within the inner lumen of the sheath having proximal and distal ends, an expandable member proximally adjacent to the distal end of the catheter which is adapted to receive on the exterior thereof an expandable stent, an inner lumen which is adapted to receive a guiding member therein and which extends between a first and second ports of the catheter; and
c) means to adjust the relative axial positions of the catheter and the sheath to expose the expandable member so that upon the expansion thereof an expandable stent disposed about the expandable member will thereby be expanded.

9. The stent delivery system kit of claim 8 including an expandable stent which is adapted to be mounted on the exterior of the expandable member on the catheter.

10. The stent delivery system of claims 8 or 9 wherein the sheath has a wall with a slit therein extending between the first and second ports thereof.

11. The stent delivery system of claims 8, 9 or 10 wherein the catheter has a wall with a slit therein extending from the second port to a location proximal to the expandable member.

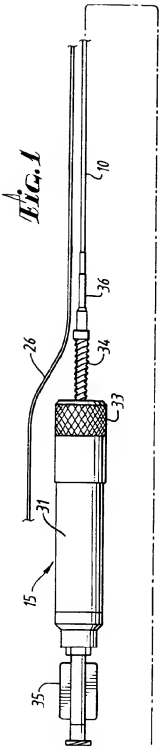


Fig. 1
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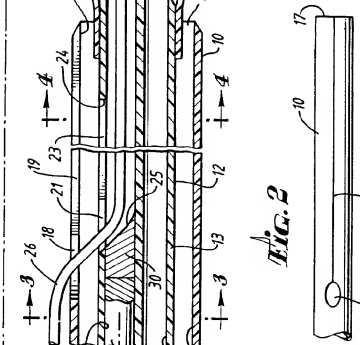
Fig. 2
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Fig. 3
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Fig. 5
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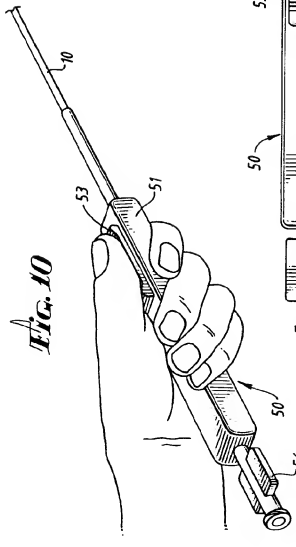

Fig. 10

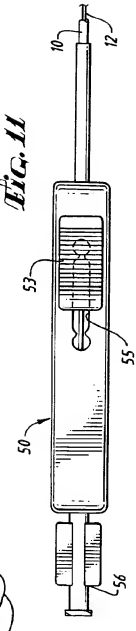

Fig. 11

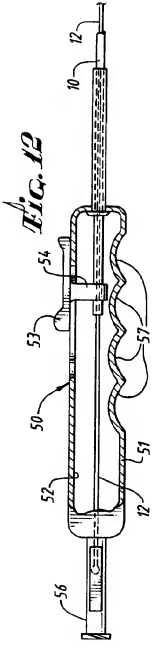

Fig. 12

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 92 10 1355

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
Y	WO-A-8 908 433 (LAZARUS) * page 5, line 25- page 6, line 36; figure 1 * ---	1,3,8,9	A 61 F 2/06
Y,D	US-A-4 748 982 (HORZEWSKI et al.) * column 5, lines 33-65; figures 1,4,6 * ---	1,3,8,9	
A	DE-A-3 640 745 (STRECKER) * column 10, line 56 - column 11, line 42; figures 1,2 * ---	1,8,9	
A	WO-A-8 901 798 (ENGINEERS AND DOCTORS) * page 3, line 30 - page 4, line 19; figure 2 * ---	1-3,8	
A	EP-A-0 408 245 (AMERICAN MEDICAL SYSTEMS) * column 5, lines 43-58; claims 1-5; figure 1 * -----	1,4,8	
			TECHNICAL FIELDS SEARCHED (Int. Cl.5) A 61 F

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
BERLIN	05-05-1992	MONNE E.M.B.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

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